DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration JEH
913062

New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

May 24, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 193219

Charles E. Nabors, Administrator
Healthcare Authority of the City of Demopolis
dba Bryan W. Whitfield Memorial Hospital
Hwy 80
Demopolis, AL 36732

Warning Letter No. 01-NSV-27

Dear Mr. Nabors:

Your facility was inspected on May 3, 2001 by a representative of the State of Alabama on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The system to communicate results is not adequate for site Healthcare Authority of the City of Demopolis because:

- There is no system in place to provide timely lay summaries
- There is no system in place to communicate serious or highly suggestive cases ASAP

Level 2

Medical audit and outcome analysis was not done separately for each individual at site Healthcare Authority of the City Demopolis

These specific deficiencies appeared on the Post Inspection Report, which was sent to your facility by the state inspector along with instructions on how to respond to these findings. These deficiencies may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

Also, it was noted during your inspection that the medical physicist survey results were not made available within the 30 day requirement. This is also a noncompliance item although the inspection software does not list this as a finding. Details concerning this and other findings were outlined in the Post Inspection Report under the "Inspector Remarks" section.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations.

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Alabama. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

Howard E. Lewis
Acting Director, New Orleans District

CED:KRS:man

cc:

Richard Glass
AL Dept. of Public Health
Office of Radiation Control
P.O. Box 303017
Montgomery, AL 36130-3017

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Director, Government Relations
c/o American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191